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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

Revised May 7, 2014
April 22, 2014

MEMORANDUM

SUBJECT: Efficacy Review for Clean Smart;
EPA Reg. No. 89896-E;
DP Barcode: D417075

FROM: Karen M. Hill, Ph.D.
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Product Science Branch
Antimicrobials Division (7510P)

THRU: Mark Perry
Team Leader
Product Science Branch
Antimicrobials Division (7510P)

TO: Demson Fuller RM32/ David Liem
Regulatory Management Branch II
Antimicrobials Division (7510P)

APPLICANT: Simple Science Limited
530 N 3rd St. #310
Minneapolis, MN. 55401

Formulation from the Label:

Active Ingredient(s):	% by wt.
Hypochlorous Acid	0.017%
Inert Ingredients	99.983%
Total	100.000%

I. BACKGROUND:

The product, CleanSmart (EPA Reg. No. 89896-E), is submitting efficacy studies in support of registration for a product as a new-end use as a disinfectant and sanitizer for use on hard non-porous surfaces in household, commercial, and institutional environments. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA dated November 26, 2013, twenty one (21) studies (MRID 492603-05 thru MRID 492603-25), EPA Form 8570-4 (CSF), and Statement of No Data Confidentiality Claims within all studies.

II. USE DIRECTIONS:

The proposed label direction for disinfection on hard non-porous environmental surfaces is given below:

(To kill 99.9% of germs on (all) hard, non-porous –or- disinfect (all) hard, non-porous surfaces.) Spray (this product) on surface (until thoroughly wet). Let stand for 10 minutes. (If desired) wipe with paper towel or clean dish towel. (Air dry. No rinsing necessary, even on food contact surfaces.) For heavily soiled surfaces, (a) precleaning (step) is required.

The proposed label direction for sanitization on hard non-porous environmental surfaces is given below:

(To kill 99.9% of germs on (all) hard, non-porous –or- disinfect (all) hard, non-porous surfaces.) Spray (this product) on surface (until thoroughly wet). Let stand for 5 minutes. (If desired) wipe with paper towel or clean dish towel. (Air dry. No rinsing necessary.) For heavily soiled surfaces, (a) precleaning (step) is required.

(To kill 99.9% of germs on (all) hard, non-porous –or- disinfect (all) hard, non-porous surfaces.) Spray (this product) on surface (until thoroughly wet). Let stand for 1 minute/60 seconds. (If desired) wipe with paper towel or clean dish towel. (Air dry. No rinsing necessary.) For heavily soiled surfaces, (a) precleaning (step) is required.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS:

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments:
The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old or all tested batches at or below the active ingredient(s) lower certified limit(s), against a mean log density of at least 6 for

Staphylococcus aureus (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants", killing on 59 out of 60 carriers for germicidal spray testing is required to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442 within ten minutes. For AOAC Use-Dilution testing, testing for each lot should be conducted on a different day. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media. The performance standard for *S. aureus* is 0-3 positive carriers out of sixty. The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty. To be deemed an effective product, the product must pass all tests for both microbes.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria):

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Sanitizing Rinses (For Previously Cleaned Food Contact Surfaces):

Sanitizing rinses may be formulated with iodophors, mixed halides, or chlorine-bearing chemicals, among other active ingredients. The effectiveness of halide sanitizing rinses for previously cleaned food contact surfaces must be substantiated by data derived from the AOAC International Chlorine (Available) in Disinfectants Germicidal Equivalent Concentration test. Data from one test on each of 3 product samples, representing 3 different batches, one of which is at least 60 days old against *Salmonella enterica* (ATCC 6539) or *Staphylococcus aureus* (ATCC 6538). Performance standard: Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product already registered as a sanitizing rinse for previously cleaned food contact surfaces. Confirmatory test standards would apply. Thus, 2 product samples, representing 2 different batches, must be tested against each

additional microorganism. It would consider and evaluate data generated from the AOAC International Chlorine (Available) in Disinfectants Germicidal Equivalent Concentration test. One sample should be evaluated for efficacy against Salmonella enterica (ATCC 6539). Performance standard: Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine. The reference standard is sodium hypochlorite.

Virucides:

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. If the product is intended to be represented as a one-step virucidal, an appropriate organic soil (i.e.- 5 percent blood serum) should be included with the viral inoculum.

Supplemental Claims:

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. COMMENTS ON THE SUBMITTED EFFICACY STUDY:

The product's Certificate of Analysis which incorporated each tested lot was provided. Testing of the active ingredients concentration was performed by Case Laboratories, Inc. at 622 Route Ten Whippany, NJ 07901. The results of the testing are given below.

Lot	Hypochlorus Acid Active Ingredient Concentration
CS001	99.5 ppm
CS002	100 ppm
CS003	102 ppm

All of the batches tested were at or below the lower certified limit of the active ingredient hypochlorous acid.

1. **MRID 492603-05, "AOAC Germicidal Spray Method," Test Organism: *Staphylococcus aureus* (ATCC 6538). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – October 24, 2013. Project Number A15677.**

The study was conducted against *Staphylococcus aureus* (ATCC 6538). Testing was conducted using three lots of test substance Clean Smart, Lot CS001, Lot CS002, and Lot CS003. Testing was performed according to the ATS Laboratory Protocol No. ECA02092413.GS (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of 10 µL aliquots from a thawed, vortex mixed stock cryovial to an initial 10 mL tube of Synthetic Broth growth medium and were incubated for 24±2 hours at 35-37°C. Following incubation, a 10µL aliquot of the culture was transferred to individual 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (Daily transfer #1). The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter, were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 53.6% relative humidity. The carriers were used within 2 hours of drying. For each lot of test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 8 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 40% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

2. **MRID 492603-06, "AOAC Germicidal Spray Method," Test Organism: *Salmonella enterica* (ATCC 10708). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – September 26, 2013. Project Number A15543.**

The study was conducted against *Salmonella enterica* (ATCC 10708). Testing was conducted using three Lots of test substance Clean Smart, Lot CS001, Lot CS002, and Lot CS003. Testing was performed according to the ATS Laboratory Protocol No. ECA02082613.GS.3 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of 10 µL aliquots from a thawed, vortex mixed stock cryovial to an initial 10 mL tube of Synthetic Broth growth medium and were incubated for 24±2 hours at 35-37°C. Following incubation, a 10µL aliquot of the culture was transferred to individual 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (Daily transfer #1). Three additional daily transfers were prepared. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture for use in testing. No soil load was

added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter, were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 50% relative humidity. The carriers were used within 2 hours of drying. The test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 45% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

3. MRID 492603-07, "AOAC Germicidal Spray Method," Test Organism: *Pseudomonas aeruginosa* (ATCC 15442). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – September 26, 2013. Project Number A15541.

The study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Testing was conducted using three Lots of test substance Brace, Lot CS001, Lot CS002 and Lot CS003. Testing was performed according to the ATS Laboratory Protocol No. ECA02082613.GS.1 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of 10 µL aliquots from a thawed, vortex mixed stock cryovial to an initial 10 mL tube of Nutrient Broth growth medium and were incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas aeruginosa* culture, a 10µL aliquot of the culture was transferred to individual 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (Daily transfer #1). Three additional daily transfers were prepared. The final test culture was incubated for 48 – 54 hours at 35-37°C. On the day of use, the *Pseudomonas aeruginosa* culture pellicle was carefully aspirated by vacuum aspiration. Care was taken to avoid disrupting the pellicle. All test cultures were vortexed and allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture for use in testing. The culture was diluted by combining 2.00 mL of test organism suspension and 2.00 mL of growth medium. No soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter, were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 50% relative humidity. The carriers were used within 2 hours of drying. The test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 44% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or

absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

4. MRID 492603-08, "AOAC Germicidal Spray Method," Test Organism: *Streptococcus pyogenes*, (ATCC 19615). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – August 29, 2013. Project Number A15433.

The study was conducted against *Streptococcus pyogenes*, (ATCC 19615). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECS02072213.GS.6 (copy provided). The product was received as ready to use (RTU) spray. From the stock plate, multiple Tryptic Soy agar plates with 5% sheep blood (BAP) were inoculated with the test organism. The plates were incubated for 2- 4 days at 35-37°C in CO_2. Following incubation, the organism was suspended in Fluid Thioglycollate Medium to target 1 x 10^8 CFU/mL. The final test culture was mixed thoroughly prior to use. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 25-30°C with 65% relative humidity. The carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 55% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps to 20 mL of Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. The vessel was shaken thoroughly. Within 25 – 60 minutes of the initial (primary) transfer, the carriers were transferred to 20 mL of secondary neutralizing media containing Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80. All subcultures were incubated for 48±2 hours at 35-37°C in CO_2. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviation or amendments were required for this study.

5. MRID 492603-09, "AOAC Germicidal Spray Method," Test Organism: Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – September 5, 2013. Project Number A15432.

The study was conducted against Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02072213.GS.4 (copy provided). The product was received as ready to use (RTU) spray. A loopful of the stock slant culture was transferred to an initial 10 mL tube of Fluid Thioglycolate growth medium, mixed, and incubated for 24±2 hours at 35-37°C. A 10 µL aliquot of this culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). One additional daily transfer was prepared. The final test culture was incubated for 48-54 hours at 35-37°C and was

mixed thoroughly prior to use. The test culture was vortexed and allowed to stand for ≥10 minutes prior to removing the upper portion leaving behind any clumps or debris and pooling the cultures in a sterile vessel for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 25-30°C with 65% relative humidity. The carriers were used within 2 hours of drying. The test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 23.4°C with 45.3% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Antimicrobial susceptibility testing was performed by ATS Labs for Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) to verify the antibiotic resistance pattern. The Kirby Bauer susceptibility assay was performed utilizing a representative culture from the day of testing and using vancomycin antibiotic disks to confirm resistance.

Note: No protocol deviation or amendments were required for this study.

6. MRID 492603-10, "AOAC Germicidal Spray Method," Test Organism: Methicillin Resistant *Staphylococcus aureus*- MRSA (ATCC 33592). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – August 29, 2013. Project Number A15430.

The study was conducted Methicillin Resistant *Staphylococcus aureus*- MRSA (ATCC 33592). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02072213.GS.2 (copy provided). The product was received as ready to use (RTU) spray. A loopful of the stock slant culture was transferred to an initial 10 mL tube of Synthetic Broth growth medium, mixed, and incubated for 24±2 hours at 35-37°C. A 10 µL aliquot of this culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). One additional daily transfer was prepared. The final test culture was incubated for 48-54 hours at 35-37°C and was mixed thoroughly prior to use. The test culture was vortexed and allowed to stand for ≥10 minutes prior to removing the upper portion leaving behind any clumps or debris and pooling the cultures in a sterile vessel for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 31 minutes at 35-37°C with 50% relative humidity. The carriers were used within 2 hours of drying. The test carriers were sprayed in a horizontal position with the test substance at a

distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 21.3°C with 49% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Antimicrobial susceptibility testing was performed by ATS Labs to verify the antibiotic resistance pattern. The Kirby Bauer susceptibility assay was performed utilizing a representative culture from the day of testing and using oxacillin antibiotic disks to confirm resistance.

7. **MRID 492603-11, "AOAC Germicidal Spray Method," Test Organism: *Listeria monocytogenes* (ATCC 19117). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – September 05, 2013. Project Number A15446.**

The study was conducted against *Listeria monocytogenes* (ATCC 19117). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02072213.GS.5 (copy provided). The product was received as ready to use (RTU) spray. A loopful of the stock slant culture was transferred to an initial 10 mL tube of Brain Heart Infusion broth, mixed, and incubated for 24±2 hours at 35-37°C. A 10 µL aliquot of this culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). Three addition daily transfers were prepared. The final test culture was incubated for 48-54 hours at 35-37°C and was mixed thoroughly prior to use. The test culture was vortexed and allowed to stand for ≥10 minutes prior to removing the upper portion leaving behind any clumps or debris and pooling the cultures in a sterile vessel for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C with 40% relative humidity. The carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 49% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to primary neutralizing solution containing 20 mL of Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80. Within approximately 25-60 minutes of the initial transfer, the carriers were transferred into individual secondary neutralizing solution containing 20 mL of Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations occurred during this study.

8. MRID 492603-12 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Herpes Simplex Virus Type 1 for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 11, 2013. Project Number A15443.

The study was conducted against the F(t) Strain of Herpes simplex virus Type t (ATCC VR-733). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.HSV1 (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot H77) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. Rabbit kidney (RK) cells (obtained from Laboratory Research Services, Inc., St. Paul, MN) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 5% heat inactivated fetal bovine serum, t0 µg/mL gentamicin, t00 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by t0-fold serial dilution and were assayed for infectivity. The RK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for seven (7) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

9. MRID 492603-13 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Herpes Simplex Virus Type 2 for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – August 30, 2013. Project Number A15429.

The study was conducted against the G Strain of Herpes simplex virus Type 2 (ATCC VR-734). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.HSV2 (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot H2-69) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. Rabbit kidney (RK) cells (obtained from Laboratory Research Services, Inc., St. Paul, MN) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 5% heat inactivated fetal bovine serum, 10 µg/mL gentamicin, t00 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of t00 x 15

mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The RK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for seven (7) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

10. MRID 492603-14 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Human Immunodeficiency Virus Type 1 for product Clean Smart, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – September 16, 2013. Project Number A15434.

The study was conducted against the HTLV-III_B Strain of Human Immunodeficiency Virus Tupe 1 (HIV-1) (obtained from Advanced Biotechnologies, Inc., Columbia, MD). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.HIV (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot HIV-11) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. MT-2 (human T-cell leukemia) cells (obtained from AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH from Dr. Douglas Richman) were used as the host cell line. Test medium used to maintain the cell cultures was RPMI-1640, supplemented with 15% heat inactivated fetal bovine serum, 50 µg/mL gentamicin, and 2.0 mM L-glutamine. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 25.0°C for 20 minutes at 42.4% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 19.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The MT-2 cells in multiwell culture dishes were inoculated in quadruplicate with 200 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for fourteen (14) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

11. MRID 492603-15 "Virucidal Efficacy of a Disinfectant for Use on Inanimate

Environmental Surfaces," Virus: Influenza A (H1N1) Virus for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – August 30, 2013. Project Number A15428.

The study was conducted against the A/PR/8/34 Strain of Influenza A (H1N1) (ATCC VR-1469). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.FLUA (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot FLUA-35) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. Rhesus monkey kidney (RMK) cells (obtained from Diagnostic Hybrids, Athens, OH) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 1% heat inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 40% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The RMK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for seven (7) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

12. MRID 492603-16 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Rhinovirus Type 37 for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 19, 2013. Project Number A15534.

The study was conducted against the 151-1 Strain of Rhinovirus Type 37 (ATCC VR-1147). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02090313.R37 (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot NR37-28) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. MRC-5 (human embryonic lung) cells (ATCC CCL-171) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 10% heat inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for

4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The MRC-5 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for seven (7) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: The reported protocol amendments were found to be acceptable. No protocol deviations were reported for this study.

13. MRID 492603-17 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Human Coronavirus for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 13, 2013. Project Number A15421.

The study was conducted against the 229E strain of Human Coronavirus (ATCC VR-740). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.COR (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot HCV-69) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. WI-38 (human lung) cells (ATCC CCL-75) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 2% heat inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The WI-38 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for twelve (12) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

14. MRID 492603-18 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Respiratory Syncytial Virus for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion

date – September 27, 2013. Project Number A15444.

The study was conducted against the Long strain of Respiratory syncytial virus (RSV) (ATCC VR-26). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.RSV (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot NRSV-30) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a t% organic soil load. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of t00 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates ($t0^{-1}$ dilution) were then titered by t0-fold serial dilution and were assayed for infectivity. The Hep-2 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for nine (9) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

15. MRID 492603-t9, "Fungicidal Germicidal Spray Method," Test Organism: *Trichophyton mentagrophytes*, (ATCC 9533). For product Clean Smart. Study conducted at ATS Labs by Anne Stemper. Study completion date – September 16, 2013. Project Number A15449.

The study was conducted against *Trichophyton mentagrophytes*, (ATCC 9533). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA020724t3.FGS.1 (copy provided). The product was received as ready to use (RTU) spray. From a stock culture of the test organism, 30 Sabouraud Dextrose Agar plates were inoculated and incubated at 25-30°C for 10 days. The mycelia were removed using a sterile device and a conidia suspension was prepared. The conidia suspension was passed through sterile gauze to remove hyphal fragments. The conidial count estimated using a hemacytometer was $8.8x10^7$ conidia/mL. The test culture was mixed thoroughly prior to use. No organic soil load was added. Individual glass slide carriers (t8 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C with 50% relative humidity. The carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 23.8°C with 36.8% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to

20 mL of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. Within 25 – 60 minutes of the initial transfer, the individual carreriers were transferred to 20 mL of secondary neutralizing subculture medium Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80. The vessel was shaken thoroughly. All neutralized subcultures were incubated for t0 days at 25-30°C. The Potato Dextrose agar plate subcultures were incubated for 44-76 hours at 25-30°C. The subculture plates were stored at 2-8°C for one day and the subculture broths were stored at 2-8°C for two days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations were required for this study.

16. MRID 492603-20, "AOAC Germicidal Spray Method," Test Organism: *Escherichia coli* (ATCC 11229). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – August 27, 2013. Project Number A15427.

The study was conducted against *Escherichia coli* (ATCC t1229). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to using ATS Laboratory Protocol No. ECA020724 t3.GS (copy provided). The product was received as ready to use (RTU) spray. A loopful of the stock slant culture was transferred to an initial t0 mL tube of Synthetic Broth, mixed, and incubated for 24±2 hours at 35-37°C. A 10 µL aliquot of this culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). One additional daily transfer was prepared. The final test culture was incubated for 48-54 hours at 35-37°C and was mixed thoroughly prior to use. The test culture was vortexed and allowed to stand for ≥t0 minutes prior to removing the upper portion leaving behind any clumps or debris and pooling the cultures in a sterile vessel for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter, were inoculated with t0.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately t square inch) of the slide and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 50% relative humidity. The carriers were used within 2 hours of drying. For each lot of test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 23°C with 53% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Letheen Broth + 0.t% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

17. MRID 492603-21, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application" Test Organism: *Staphylococcus aureus* (ATCC 6538). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – October 24, 2013. Project Number

A15678.

The study was conducted against *Staphylococcus aureus* (ATCC 6538). Testing was conducted using three lots of test substance Clean Smart, Lot CS001, Lot CS002, and Lot CS003. Testing was performed according to ATS Laboratory Protocol No. ECA02092413.NFS.1 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of Nutrient Broth growth medium for the initial suspension. From the initial suspension, a minimum of three daily loopful (10 µL) transfers of culture into 10 mL of Nutrient Broth was performed and each was incubated for 24 ± 2 hours. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 15 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 35 minutes at 35-37°C and with 40% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 8 sprays. The carriers were allowed to remain wet for 5 minutes at 21°C with 42% relative humidity. Following the exposure period, the individual carriers were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of neutratlized solution (10^0) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 35-37°C prior to visual enumeration. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

18. MRID 492603-22, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application" Test Organism: *Enterobacter aerogenes* (ATCC 13048). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – October 24, 2013. Project Number A15679.

The study was conducted against *Enterobacter aerogenes* (ATCC 13048). Testing was conducted using three lots of test substance Clean Smart, Lot CS001, Lot CS002, and Lot CS003. Testing was performed according to ATS Laboratory Protocol No. ECA02092413.NFS.2 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of Tryptic Soy Broth growth medium for the initial suspension. From the initial suspension, a minimum of three daily loopful (10 µL) transfers of culture into 10 mL of Tryptic Soy Broth was performed and each was incubated for 24 ± 2 hours. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 15 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 35 minutes at 35-37°C and with 41% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 8 sprays. The carriers

were allowed to remain wet for 5 minutes at 22°C with 41% relative humidity. Following the exposure period, the individual carriers and excess liquid were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of neutralized solution (10°) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 25-30°C prior to visual enumeration. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

19. MRID 492603-23, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application" Test Organism: *Streptococcus pneumoniae* (ATCC 6305). For product Clean Smart. Study conducted at ATS Labs by Jill Ruhme. Study completion date – September 11, 2013. Project Number A15442.

The study was conducted against *Streptococcus pneumoniae* (ATCC 6305). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02071913.NFS.6 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of multiple Tryptic Soy Agar with 5% Sheep Blood plate and incubating for 2-4 days at 35-37°C. Following incubation, an organism suspension was prepared in Fluid Thioglycollate medium that target 1 X 10^8 CFU/mL. No organic soil load was added. The test culture is used within three hours of preparation. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 20-40 minutes at 35-37°C and with 40-41% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 8 sprays. The carriers were allowed to remain wet for 30 seconds at 22°C with 41% relative humidity. Following the exposure period, the individual carriers and excess liquid were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of neutralized solution (10°) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 35-37°C prior to visual enumeration. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

20. MRID 492603-24, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application" Test Organism: *Salmonella enterica* (ATCC 10708). For product Clean Smart. Study conducted at ATS Labs by Joshua Luedtke. Study completion date – September 4, 2013. Project Number A15441.

The study was conducted against *Salmonella enterica* (ATCC 10708). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02071913.NFS.3 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of Nutrient Broth growth

medium for the initial suspension. From the initial suspension, a minimum of three daily loopful (10 µL) transfers of culture into 10 mL of Nutrient Broth were performed and each was incubated for 24 ± 2 hours. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 15 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 40% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 30 seconds at 22°C with 58% relative humidity. Following the exposure period, the individual carriers and excess liquid were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of neutratlized solution (10°) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 35-37°C prior to visual enumeration. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: The protocol amendments were found to be acceptable. There were not any protocol deviations reported.

21. MRID 492603-25, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application" Test Organism: Methicillin Resistant *Staphylococcus aureus*- MRSA (ATCC 33592). For product Clean Smart. Study conducted at ATS Labs by Joshua Luedtke. Study completion date – September 6, 2013. Project Number A15447.

The study was conducted against Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02071913.NFS.4 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of Synthetic Broth growth medium for the initial suspension. From the initial suspension, a minimum of three daily loopful (10 µL) transfers of culture into 10 mL of Synthetic Broth were performed and each was incubated for 24 ± 2 hours. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 15 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 35 minutes at 35-37°C and with 40% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 30 seconds at 22.2°C with 43.59% relative humidity. Following the exposure period, the individual carriers and excess liquid were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization,

duplicate 1.00 mL and 0.100 mL aliquots of neutratlized solution (10°) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were placed at 2-8°C for two days. Following incubation and storage, the subcultures were visually enumerated. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Antibiotic susceptibility testing was performed by ATS Labs using the Kirby Bauer susceptibility assay. Oxacillin antibiotic disks were used to verify antimicrobial resistance pattern.

Note: The protocol amendments were found to be acceptable. There were not any protocol deviations reported.

22. MRID 492603-26, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (Modification of Spray Product Application", Test Organism: Vancomycin Resistant *Enterococcus faecalis*- VRE (ATCC 51575)", for product Clean Smart, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – September 03, 2013. Project Number A15440.

The study was conducted against Vancomycin Resistant *Enterococcus faecalis*- VRE (ATCC 51575). Two lots of the product Clean Smart, Lot CS001 and Lot Lot CS002, were tested using the provided ATS Labs protocol ECA02071913.NFS.2 marked as proprietary information. The product was received as a ready-to-use trigger spray. The test culture was prepared by inoculating 10 mL of Fluid Thioglycollate media from a stock slant with no more than 5 transfers from freeze and ≤30 days old. Daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL from the initial broth suspension into 10 mL of culture media were performed. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred. No soil load was added. Glass carriers (1" X 1") were inoculated uniformly spread over the entire carrier slide with 20 µL of the 48 - 54 hours old suspension of test organism. The carriers were dried for 21 minutes at 35 - 37°C with 40% relative humidity. Each carrier was sprayed with the product for 5 sprays at a distance of 4-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 23.1°C with 45.6% relative humidity. Following exposure, the individual carriers and excess liquid in each Petri dish were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization , duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery Tryptic Soy Agar with 5% Sheep Blood. All subcultures were incubated for 48 ± 4 hours at 35 - 37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic resistance confirmation, and carrier population.

Note- ATS Labs verified Vancomycin Resistant Enterococcus faecalis is resistant to vancomycin by performing a Kirby Bauer Susceptibility assay. Oxacillin antibiotic disks were used to verify antimicrobial resistance pattern.

23. MRID 492603-27, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (Modification of Spray Product Application", Test Organism: *Escherichia coli* (ATCC 11229)", for product Clean Smart, by Anne Stemper. Study conducted at ATS Labs. Study completion date – August 30, 2013. Project Number A15448.

The study was conducted against *Escherichia coli* (ATCC 11229). Two lots of the product Clean Smart, Lot CS001 and Lot Lot CS002, were tested using the provided ATS Labs protocol ECA02071913.NFS.5 marked as proprietary information. The product was received as a ready-to-use trigger spray. The test culture was prepared by inoculating 10 mL of Synthetic Broth from a stock slant with no more than 5 transfers from freeze and ≤30 days old. Daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL from the initial broth suspension into 10 mL of culture media were performed. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred. No soil load was added. Glass carriers (1" X 1") were inoculated uniformly spread over the entire carrier slide with 20 µL of the 48 - 54 hours old suspension of test organism. The carriers were dried for 30 minutes at 35 - 37°C with 40% relative humidity. Each carrier was sprayed with the product for 5 sprays at a distance of 4-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 22°C with 49% relative humidity. Following exposure, the individual carriers and excess liquid in each Petri dish were transferred to 20 mL of Letheen Broth + 0.01% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization , duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10^0) were plated onto the recovery Tryptic Soy Agar with 5% Sheep Blood. All subcultures were incubated for 48 ± 4 hours at 35 - 37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic resistance confirmation, and carrier population.

24. MRID 492603-28 "AOAC Available Chlorine in Disinfectants" against *Staphylococcus aureus* (ATCC 6538), for Clean Smart 01, by Matthew Sathe; Project number: A15457. Study conducted at ATS Labs. Study completed on September 6, 2013.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) grown in Nutrient Broth. Three lots (CS001, CS002, and CS003) of the product, Clean Smart 01, were tested according to ATS Labs Protocol No. ECA02072213.AVC.2 (copy provided). The product was received ready-to-use. Sodium hypochlorite (NaOCl) was used as the data control standard at three concentrations, 200 ppm (titrated at 199 ppm), 100 ppm, and 50 ppm. Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 was used as neutralizer; and Tryptic Soy Agar with 5% sheep blood was used as agar plate medium. A 0.05 ml aliquot of the test culture was added to each (10 ml) of the test substance and control NaOCl solutions at 20±1°C. One minute after addition of the test organism, 10 µL of each medicated and control culture was transferred to 10 ml of neutralizing subculture medium. Each tube was then challenged with additional 0.05 ml aliquot of the test culture 30 seconds after subculturing. This process was repeated for a total of 10 subcultures for each lot and control. The neutralized subcultures were incubated for 48±2 hours at 35-37°C, stored at 2-8°C for one day, and examined for the presence or absence of visible growth. Representative neutralized subcultures showing growth were

subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per ml in the initial suspension population is ***Staphylococcus aureus* 3.6 x 10^8**.

25. MRID 492603-29 "AOAC Available Chlorine in Disinfectants" against *Salmonella enterica* serovar Typhi (ATCC 6539), for Clean Smart 01, by Matthew Sathe; Project number: A15456. Study conducted at ATS Labs. Study completed on September 5, 2013.

This study was conducted against *Salmonella enterica* serovar Typhi (ATCC 6539) grown in Nutrient Broth. Three lots (CS001, CS002, and CS003) of the product, Clean Smart 01, were tested according to ATS Labs Protocol No. ECA02072213.AVC.1 (copy provided). The product was received ready-to-use. Sodium hypochlorite (NaOCl) was used as the data control standard at three concentrations, 200 ppm (titrated at 199 ppm), 100 ppm, and 50 ppm. Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 was used as neutralizer; and Tryptic Soy Agar with 5% sheep blood was used as agar plate medium. A 0.05 ml aliquot of the test culture was added to each (10 ml) of the test substance and control NaOCl solutions at 20±1°C. One minute after addition of the test organism, 10 µL of each medicated and control culture was transferred to 10 ml of neutralizing subculture medium. Each tube was then challenged with additional 0.05 ml aliquot of the test culture 30 seconds after subculturing. This process was repeated for a total of 10 subcultures for each lot and control. The neutralized subcultures were incubated for 48±2 hours at 35-37°C, stored at 2-8°C for one day, and examined for the presence or absence of visible growth. Representative neutralized subcultures showing growth were subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per ml in the initial suspension population is ***Salmonella enterica* serovar Typhi 5.0 x 10^8**.

26. MRID 492603-30 "AOAC Available Chlorine in Disinfectants" against *Escherichia coli* (ATCC 11229), for Clean Smart 01, by Jill Ruhme; Project number: A15458. Study conducted at ATS Labs. Study completed on September 13, 2013.

This study was conducted against *Escherichia coli* (ATCC 11229) grown in Synthetic Broth. Two lots (CS001 and CS002) of the product, Clean Smart 01, were tested according to ATS Labs Protocol No. ECA02072213.AVC.3 (copy provided). The product was received ready-to-use. Sodium hypochlorite (NaOCl) was used as the data control standard at three concentrations, 200 ppm (titrated at 199 ppm), 100 ppm, and 50 ppm. Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 was used as neutralizer; and Tryptic Soy Agar with 5% sheep blood was used as agar plate medium. A 0.05 ml aliquot of the test culture was added to each (10 ml) of the test substance and control NaOCl solutions at 20±1°C. One minute after addition of the test organism, 10 µL of each medicated and control culture was transferred to 10 ml of neutralizing subculture medium. Each tube was then challenged with additional 0.05 ml aliquot of the test culture 30 seconds after subculturing. This process was repeated for a total of 10 subcultures for each lot and control. The neutralized subcultures were incubated for 48±2 hours at 35-37°C, stored at 2-8°C for one day, and examined for the presence or absence of visible growth. Representative neutralized subcultures showing growth were

subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per ml in the initial suspension population is ***Escherichia coli*** **8.0 x 10^8**.

V. RESULTS:

MRID #	ORGANISM	RESULTS @10 Minutes Exposure Number of Carriers Exhibiting Growth/Total Number of Carriers Tested			Carrier Population Control (Average Log_{10})
		Lot CS001	Lot CS002	Lot CS003	
492603-05	*Staphylococcus aureus*	0/60	0/60	0/60	5.64
492603-06	*Salmonella enterica*	0/60	0/60	0/60	6.37
492603-07	*Pseudomonas aeruginosa*	0/60	0/60	0/60	6.09
492603-08	*Streptococcus pyogenes*	1°= 0/10 2°=0/10	1°= 0/10 2°=0/10		6.34
492603-09	*Enterococcus faecalis*-VRE	0/10	0/10		5.77
492603-10	*Staphylococcus aureus*-MRSA	0/10	0/10		6.21
492603-11	*Listeria monocytogenes*	1°= 0/10 2°=0/10	1°= 0/10 2°=0/10		4.75
492603-19	*Trichophyton mentagrophytes*	1°= 0/10 2°=0/10	1°= 0/10 2°=0/10		5.10
492603-20	*Escherichia coli*	0/10	0/10		5.84

MRID #	ORGANISM	RESULTS (Log) @10 Minutes Exposure			Dried Virus Control (Log)
		$TCID_{50}$/	Lot CS001	Lot CS002	
492603-12	Herpes Simplex Virus Type 1	100µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$10^{5.25}$
492603-13	Herpes Simplex Virus Type 2	100µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$10^{4.50}$
492603-14	Human Immunodeficiency Type 1	200µL Cytotoxicity seen at 10^{-1}	$\leq 10^{1.50}$	$\leq 10^{1.50}$	$10^{5.50}$
492603-15	Influenza A (H1N1) Virus	100µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$10^{6.50}$
492603-16	Rhinovirus Type 37	100µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$10^{4.75}$
492603-17	Human Coronavirus	100µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$10^{4.50}$
492603-18	Respiratory Syncytial Virus	100µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	$10^{4.75}$

MRID #	ORGANISM @5 minutes exposure	RESULTS Geometric Mean CFU/Carrier (Log)			Carrier Population Geometric Mean (Average Log_{10})	% Reduction for all lots tested
		Lot CS001	Lot CS002	Lot CS003		
492603-21	*Staphylococcus aureus*	$<2.00 \times 10^1$	$<2.00 \times 10^1$	$<2.00 \times 10^1$	2.69×10^6	>99.9%
492603-22	*Enterobacter aerogenes*	$<2.00 \times 10^1$	$<2.00 \times 10^1$	$<2.00 \times 10^1$	1.70×10^7	>99.9%
MRID #	**ORGANISM @ 30 seconds exposure**					
492603-23	*Streptococcus pneumonia*	$<2.63 \times 10^1$	$<4.07 \times 10^1$		7.59×10^5	>99.9%
492603-24	*Salmonella enterica*	$<2.00 \times 10^1$	$<2.00 \times 10^1$		1.78×10^6	>99.9%
492603-25	*Staphylococcus aureus*-MRSA	$<2.00 \times 10^1$	$<2.00 \times 10^1$		3.47×10^6	>99.9%
492603-26	*Enterococcus faecalis*-VRE	$<2.00 \times 10^1$	$<2.00 \times 10^1$		2.14×10^6	>99.9%
492603-27	*Escherichia coli*	$<2.00 \times 10^1$	$<2.00 \times 10^1$		1.48×10^7	>99.9%

MRID	Test Organism	Test/Control Substance	Concentration or Lot	Subculture Number									
				1	2	3	4	5	6	7	8	9	10
492603-28	*Staphylococcus aureus* (ATCC 6538)	NaOCl	200 ppm	0	0	0	0	0	0	+	+	+	+
			100 ppm	0	0	0	0	+	+	+	+	+	+
			50 ppm	0	0	+	+	+	+	+	+	+	+
		Clean Smart 01	Lot CS001	0	0	0	0	0	0	0	0	0	+
			Lot CS002	0	0	0	0	0	0	0	0	0	0
			Lot CS003	0	0	0	0	0	0	0	0	0	+
492603-29	*Salmonella enterica* serovar Typhi (ATCC 6539)	NaOCl	200 ppm	0	0	0	0	0	0	+	+	+	+
			100 ppm	0	0	0	0	+	+	+	+	+	+
			50 ppm	0	0	+	+	+	+	+	+	+	+
		Clean Smart 01	Lot CS001	0	0	0	0	0	0	0	0	+	+
			Lot CS002	0	0	0	0	0	0	0	0	0	+
			Lot CS003	0	0	0	0	0	0	0	0	+	+
492603-30	*Escherichia coli* (ATCC 11229)	NaOCl	200 ppm	0	0	0	0	0	+	+	+	+	+
			100 ppm	0	0	+	+	+	+	+	+	+	+
			50 ppm	0	+	+	+	+	+	+	+	+	+
		Clean Smart 01	Lot CS001	0	0	0	0	0	0	+	+	+	+
			Lot CS002	0	0	0	0	0	0	0	+	+	+

+ = Growth of the test organism
0 = No growth of the test organism

VI. CONCLUSIONS:

1.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a disinfectant against the following microorganisms on hard, non-porous surfaces with a 10-minute contact time:

Staphylococcus aureus	MRID 492603-05
Salmonella enterica	MRID 492603-06
Pseudomonas aeruginosa	MRID 492603-07
Streptococcus pyogenes	MRID 492603-08
Enterococcus faecalis-VRE	MRID 492603-09
Staphylococcus aureus-MRSA	MRID 492603-10
Listeria monocytogenes	MRID 492603-11
Escherichia coli	MRID 492603-20

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Antibiotic susceptibility testing demonstrated antibiotic resistance.

2.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a disinfectant against the following fungi on hard, non-porous surfaces with a 10-minute contact time:

Trichophyton mentagrophytes	MRID 492603-19

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a disinfectant against the following viruses on hard, non-porous surfaces with a 1% organic soil load for a 10- minutes contact time:

Herpes Simplex Virus Type 1	MRID 492603-12
Herpes Simplex Virus Type 2	MRID 492603-13
Human Immunodeficiency Type 1	MRID 492603-14
Influenza A (H1N1) Virus	MRID 492603-15
Rhinovirus Type 37	MRID 492603-16
Human Coronavirus	MRID 492603-17
Respiratory Syncytial Virus	MRID 492603-18

Complete inactivation was demonstrated or at least a 3-log reduction in titer was shown beyond the cytotoxic level. Recoverable virus titers of at least 10^4 were achieved. Neutralization control demonstrated growth.

4.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a non-food contact sanitizer for use on hard, non-porous surfaces with bactericidal activity against the following microorganisms for a 5- minutes contact time:

Staphylococcus aureus	MRID 492603-21
Enterobacter aerogenes	MRID 492603-22

Results demonstrate a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Sterility controls did not show growth.

5.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a non-food contact sanitizer for use on hard, non-porous surfaces with bactericidal activity against the following microorganisms for a 30 seconds contact time:

Streptococcus pneumonia	MRID 492603-23
Salmonella enterica	MRID 492603-24
Staphylococcus aureus-MRSA	MRID 492603-25
Enterococcus-faecalis – VRE	MRID 492603-26
Escherichia coli	MRID 492603-27

Results demonstrate a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Sterility controls did not show growth. Antibiotic susceptibility testing demonstrated antibiotic resistance.

6.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a food contact sanitizer for use on hard, non-porous surfaces with bactericidal activity against the following microorganisms for a 1 minute contact time:

Escherichia coli	MRID 492603-28
Staphylococcus aureus	MRID 492603-29
Salmonella enterica	MRID 492603-30

Test results showed product concentrations equivalent in activity to 200 ppm of available chlorine. Neutralization confirmation testing and viability control showed positive growth of the microorganisms. Purity controls were reported as pure.

VII. RECOMMENDATIONS:

1.) The product label proposes that the ready to use spray product Clean Smart is a disinfectant against the following microorganisms on hard, non-porous surfaces with a 10-minute contact time:

Staphylococcus aureus	(ATCC 6538)
Salmonella enterica	(ATCC 10708)

Pseudomonas aeruginosa	(ATCC 15442)
Streptococcus pyogenes	(ATCC 19615)
Enterococcus faecalis-VRE	(ATCC 51575)
Staphylococcus aureus-MRSA	(ATCC 33592)
Listeria monocytogenes	(ATCC 19117)
Escherichia coli	(ATCC 11229)

These claims are **acceptable** as they are supported by the submitted data.

2.) The product label proposes that the ready to use spray product Clean Smart is a disinfectant with fungicidal activity against the following organism on hard, non-porous surfaces with a 10-minute contact time:

Trichophyton mentagrophytes	(ATCC 9533)

These claims are **acceptable** as they are supported by the submitted data.

3.) The product label proposes that the ready to use spray product Clean Smart is a disinfectant with virucidal activity against the following organisms on hard, non-porous surfaces with a 10-minute contact time:

Herpes Simplex Virus Type 1	(ATCC VR-733)
Herpes Simplex Virus Type 2	(ATCC VR-734)
Human Immunodeficiency Type 1	(Advanced Biotechnologies)
Influenza A (H1N1) Virus	(ATCC VR-1469)
Rhinovirus Type 37	(ATCC VR-1147)
Human Coronavirus	(ATCC VR-740)
Respiratory Syncytial Virus	(ATCC VR-26)

These claims are **acceptable** as they are supported by the submitted data.

4.) The product label proposes that the ready to use spray product Clean Smart is a non-food contact sanitizer against the following organisms on hard non-porous surfaces with a 5 minute contact time:

Staphylococcus aureus	(ATCC 6538)
Enterobacter aerogenes	(ATCC 13048)

These claims are **acceptable** as they are supported by the submitted data.

5.) The product label proposes that the ready to use spray product Clean Smart is a non-food contact sanitizer against the following organisms on hard non-porous surfaces with a 30 seconds contact time:

Streptococcus pneumonia	(ATCC 6305)
Salmonella enterica	(ATCC 10708)
Staphylococcus aureus-MRSA	(ATCC 33592)

Enterococcus faecalis- VRE	(ATCC 51575)
Escherichia coli	(ATCC 11229)

These claims are **acceptable** as they are supported by the submitted data.

6.) The product label proposes that the ready to use spray product Clean Smart is a food contact sanitizer against the following organisms on hard non-porous surfaces with a 1 minute contact time:

Escherichia coli	(ATCC 11229)
Staphylococcus aureus	(ATCC 6538)
Salmonella enterica	(ATCC 10708)

These claims are **acceptable** as they are supported by the submitted data.

LABEL RECOMMENDATIONS:

- Page 1- remove all hospital/healthcare sanitizer claims. Sanitizing claims are not acceptable for hospital use.
- Page 1- remove air disinfection claim. This is false and misleading. Data was not submitted to support this claim.
- Page 1- remove the term "Everywhere". This is misleading. The product has been approved for use on hard non-porous surfaces which are not located everywhere.
- Under General Claims:
  - Remove all "quick" and all "fast" sanitization or disinfection references on the label as these claims are supported by 5 and 10 minute data, respectively.
  - Remove all references to use on produce and references to use on fruits and vegetables.
  - Remove the terms "everywhere" and "anywhere" from sanitization or disinfection statements as they imply product can be used on surfaces other than hard, non-porous surfaces.
- Under direction for use as a Sanitizer, rewrite "non-food surfaces' to state "non-food hard non-porous surfaces"
- Soak/immersion directions must be removed from label. The data submitted supports spray use only. Use dilution method was not used in the submitted studies to support soak/immersion claims.
- Page 6, remove the brackets around on hard, non-porous surfaces in the statement "Can reduce the spread of illness-causing (kitchen) bacteria (on hard, non-porous surfaces)". In order to make this claim, "on hard, non-porous surfaces" must be stated.
- Page 6, remove "(Gently) (lightly)". This is misleading. These claims have not been substantiated.
- Throughout the proposed label the word "bacteria" must be qualified with the approved microorganisms for non-food contact sanitization and disinfection on hard non-porous surfaces.
- Page 6, remove "without leaving a harmful chemical residue". Data was not submitted to support this claim.

- Page 6, the surfaces in the statement "(Kills) (eliminates) (destroys) (removes) 99.9% of bacteria on commonly touched surfaces that can be transfer points for bacteria" must be qualified to state hard non-porous surfaces.
- Page 6, remove the following claims:
  ""(Kills) (eliminates) (destroys) (removes) 99.9% of bacteria that (antibacterial) dish soap leaves behind"
  ""(Kills) (eliminates) (destroys) (removes) 99.9% of bacteria that (antibacterial) dish soap can spread around"
  ""(Kills) (eliminates) (destroys) (removes) 99.9% of bacteria, including *E. coli* and *Salmonella* that (antibacterial dish soap leaves behind and spread around"
  These claims are misleading. It implies that antibacterial dish soap leads to the presence/existence of microorganisms.
- Page 7, rewrite the statement "Kills germs while it cleans" to state "Cleans while it kills germs". The killing of germs requires a contact time whereas cleaning does not. Therefore, cleaning uses cannot promote killing of germs.
- Page 11-remove HAI and OSHA references. This implies endorsement.
- Page 11- revise cross-contamination claim to include "on hard non-porous surfaces".
- Page 12- remove cleans and disinfects in one step. Disinfection requires a contact time whereas cleaning does not.
- Page t2- remove Appendix A reference and insert an appropriate organism reference list. Appendix A reference list was not included in the label.
- Page 12- remove the statement "[Product Name] [This Product] has demonstrated effectiveness against influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 [(formerly called swine flu)]". This is misleading as data was not submitted to support the claim.
- Page 12- remove "Kills cold and flu viruses" or qualify the statement with the approved organisms associated with each claim.
- Page 12- the term "Virucidal" and "Fungicidal" must be qualified.
- Page 12- remove the statement "Immerse handling and restraining equipment such as leashes, muzzles, halters, or ropes". This is misleading. Data was not submitted to support an immersion claim and the listed equipment are not considered hard non-porous surfaces.